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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,802	06/19/2003	Jennie P. Mather	415072002500	9712

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,802	MATHER ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group A. Claims 1-2, 12-15, drawn to an antibody to RAAG10, classified in class 530, subclass 387.1.

Group B. Claims 3-11, drawn to a nucleic acid encoding an antibody to RAAG10, classified in class 536, subclass 23.1.

Group C. Claims 16-21, drawn to a method for treating cancer, using an anti-RAAG10 antibody, classified in class 424, subclass 130.1. A method for treating each of the cancer cited in claim 16 constitutes a single, distinct invention.

Group D. Claim 22, drawn to a method for detecting cancer, using an anti-RAAG10 antibody, classified in class 435, subclass 7.1. A method for detecting each of the cancer cited in claim 22 constitutes a single, distinct invention.

Group E. Claims 23-24, drawn to an agent that blocks the interactions between RAAG10 and RAAG10 binding partner, classified in class 435, subclass 7.1.

This application contains claims 1-2, 12-15 of Group A, and claims 3-11 of Group B directed to the following patentably distinct **species**:

Claims 1-2, 12-15 of Group A, and claims 3-11 of Group B are generic to the following species:

Any one of the cancers cited in claim 2.

Further, claims 1-24 of groups A-E are directed to the following patentably distinct species:

Claims 1-24 are generic to the following species:

An antibody binding to the epitope A, B, or C, produced by a hybridoma having a deposit number of ATCC No. PTA-4217, PTA-4218, (PTA-4244, or PTA-4245), as disclosed in the specification on pages 5, 62.

The inventions are distinct, each from each other because of the following reasons:

A. Inventions A, B and E represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects.

The antibodies, the nucleic acids and antagonist agents blocking interactions between RAAG10 and RAAG10 binding partner are all structurally distinct molecules and chemically different from each other. The antibody is made by expression of a hybridoma, the polynucleotide is made by recombinant method, while the blocking agent made by chemical synthesis. Further, the antibody can be used for antibody binding detection, the polynucleotide can be used for hybridization screening, the blocking agent can be used for methods of treatment. Furthermore, neither of the inventions is essential for the production of the other, and they have different modes of operation, different functions, and different effects. While an antibody can made by methods using the corresponding polynucleotide, it can also be recovered from a natural source using biochemical means. For instant, the antibody can be isolated from natural source, using biochemical means..

Searching all the antibodies, the polynucleotides, and the blocking agents would cause serious burden. In the instant case, the search of all the antibodies, the polynucleotides, and the blocking agents are not coextensive. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to the antibody which would not have described the polynucleotide, or the blocking agent. As such, it would be burdensome to search the inventions of Groups A-B, E together.

B. The inventions of Groups C-D are materially distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The inventions of Groups C-D are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The method of diagnosis of different cancers and a method of treating different cancers are all unrelated as they have different modes of operation, and differ in method steps and reagents used. For diagnosis of cancer, using an antibody, quantitation of a labeled antibody that binds specifically to the target polypeptide may be used. For treatment of cancer, an antibody is administered to a patient having the disease, using any mode of administration. Further, for diagnosing or treating different cancers, different population of target patients are used. Thus, each group is unrelated as they comprise distinct steps and utilize different products, which demonstrates that each method has different mode of operation. For these reasons the Inventions C-D are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The examination of all groups would require different searches in the U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. There may be journal articles devoted solely to detecting the presence of one cancer, which would not have described methods of detecting the presence of another cancer, or a method of treating cancer, or vice versa . Moreover, even if the method for detecting cancer were known, the method of treating using the same products may be novel and unobvious, in view of the preamble and active steps. As such, it would be burdensome to search the inventions of Groups C-D together.

C. The inventions of Group A and Groups (C, D) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody binding agent can be used to make affinity column, as opposed to treating a disorder.

Searching the inventions of Groups (A), (C-D) together would impose serious search burden. The inventions of Groups (A), (C,D) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibody and the method of diagnosing or treating cancer, using the antibody, are not coextensive. In addition, the search for Groups (C, D) would require a text search for the method of diagnosing or treating cancer, in addition to a search for the antibody. Moreover, even if the antibody product were

known, the method of diagnosing or treating cancer, which uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Groups (B, E) and Groups (C, D) are unrelated because the product of groups (B, E) is not used or otherwise involved in the processes of groups (C, D).

The species cancers are distinct, because they are different cancers, with different etiology and characteristics.

The species antibodies are distinct, because they are different antibodies binding to different epitopes.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

If any one of groups A-E were elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
March 14, 2007

SHANON FOLEY
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